UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01-12257-PBS** **Subcategory Case No. 06-11337**
THIS DOCUMENT RELATES TO: *State of California, ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al.* Case No: 1:03-cv-11226-PBS	**Judge Patti B. Saris** **Magistrate Judge Marianne B. Bowler**

PLAINTIFFS' SUR-REPLY IN OPPOSITION TO DEFENDANTS' JOINT BRIEF IN SUPPORT OF THEIR MOTIONS FOR PARTIAL SUMMARY JUDGMENT

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INTRODUCTION

This case, brought under the California False Claims Act ("CA FCA"), focuses on liability and damages alleged by California regarding falsely inflated AWPs set by Defendants Dey, Mylan and Sandoz for certain generic drugs, comprised of 394 NDCs. California's damages, which are attributable to approximately 24.5 million false claims paid to pharmacy providers for Defendants' drugs between **January 1994** and **December 2004**, are based on the overpayments caused by Defendants' grossly inflated AWPs. Plaintiffs' expert has calculated total single (i.e., non-trebled) damages of just over $277 million.[1] Dey's 28 NDCs, for over 62% of the relevant period, exhibited AWP spreads of at least 300%, with some greater than 800%. (CA Dey SOF ¶ 25.[2]) Mylan's and Sandoz's NDCs (217 and 149, respectively) exhibited AWP spreads, for at least 80% of the relevant period, of at least 300%, with some greater than 2000%. (CA Mylan SOF ¶ 24, CA Sandoz SOF ¶ 24).

Momentarily setting aside the onslaught of legal argument, factual narratives, and supporting exhibits proffered by both sides in summary judgment briefing on this case, it is important to highlight a few core facts Defendants would prefer that the Court ignore. Medi-Cal, like all other state Medicaid programs, exists for one reason: to provide healthcare for the most vulnerable citizens in our society—children, indigents under age 65, and those with critical diseases such as HIV/AIDs. Such beneficiaries—who number more than six million in California alone—are in some respects *federal* as much as state "protectees," given the two sovereigns' mutual authority and shared responsibilities with regard to implementing and

[1] *See* Declaration of Nicholas N. Paul in Support of Plaintiffs' Opposition to Defendants' Joint Motion for Partial Summary Judgment (docket no. 6791) ("Paul Decl."), at Ex. 11 (12/18/09 Leitzinger Declaration, see Ex. A thereto (Dey report) at 4; Ex. B (Mylan report) at 4; Ex. C (Sandoz report) at 4.) The CA FCA imposes mandatory treble damages, and penalties of $5,000 to $10,000 per false claim. *See* CAL. GOV'T CODE § 12651(a).

[2] Plaintiffs' Local Rule 56.1 Statement of Undisputed Material Facts as to Defendants Dey, L.P. and Dey, Inc. ("CA Dey SOF") (docket no. 6691), as to Defendants Mylan Laboratories Inc. and Mylan Pharmaceuticals Inc. ("CA Mylan SOF") (docket no. 6689), and as to Defendant Sandoz Inc. ("CA Sandoz SOF") (docket no. 6687).

overseeing the operation of Medicaid programs.[3] Like most vast government entitlement programs, there is no doubt that Medi-Cal (and, specifically, its drug reimbursement program) could be run more efficiently. However, the fact that Medi-Cal is not run with the pecuniary precision of a for-profit manufacturing business does not obviate the fact that monies which are siphoned from the program due to systematic fraud (such as deliberately false AWP pricing) serve to increasingly drain the public fisc and, in turn, strain the safety net upon which millions of Medi-Cal beneficiaries rely. Every instance of fraud erodes the finite resources underpinning the availability of health care for a sizeable population of disadvantaged people.

There is no disputing the fact that all three Defendants have used the Medi-Cal drug reimbursement system as a vehicle for boosting sales and profits by either deliberately inflating AWPs for their drugs or by exploiting the gaps between their drugs' AWPs and actual acquisition costs in order to increase providers' potential profits. The only questions are whether Defendants have acted in violation of the California False Claims Act, and whether they may circumvent liability for their conduct by way of the government knowledge defense. The answers are yes and no, respectively, for the reasons discussed below.

ARGUMENT

I. THE NINTH CIRCUIT'S DECISION IN *ORTHOPAEDIC HOSPITAL* DOES NOT RELIEVE DEFENDANTS OF LIABILITY.

Defendants' reply argument concerning scienter and causation is partially focused on the Ninth Circuit's decision in *Orthopaedic Hospital v. Belshe*, 103 F.3d 1491 (9th Cir. 1997), *cert.*

[3] As noted in Plaintiff's Memorandum in Support of their Motion for Partial Summary Judgment at 2, Medi-Cal is the main source of health insurance for about 6.8 million people, and accounted for 19% of California's General Fund spending in fiscal year 2008-2009. Medi-Cal is the largest Medicaid program in the United States in terms of people served, the second largest in terms of dollars spent ($47 billion annually), and the primary (if not exclusive) source of health coverage for one in ten individuals under 65, one in three of the State's children, and the majority of AIDS patients. (California Healthcare Foundation, *California Healthcare Almanac: Medi-Cal Facts and Figures*, p. 2, (September 2009), in pdf format at http://www.chcf.org/documents/policy/MediCalFactsAndFigures2009.pdf (or http://tiny.cc/Qe3tl).

denied, 422 U.S. 104 (1998). Defendants' theory, while novel, is a classic red herring. Stripped of hyperbole, Defendants' argument is this:

- Following the issuance of *Orthopaedic Hospital* in 1997 (which exclusively addressed a challenge to *hospital reimbursement* rates) it was California's obligation to ensure that Medi-Cal's prescription drug reimbursement rates were consistent with Medicaid's goals of efficiency, economy, quality service, and access, as provided by Section 30(A) of the Federal Medicaid Act.

- "In 1997, 1998, and 2000, California considered, but ultimately did not adopt, changes to Medi-Cal reimbursement methodology such as increasing the discount of AWP or using WAC to calculate reimbursement." (Defs. Jt. Reply Br. at 7.) In 1999, the California Legislature directed that Medi-Cal conduct a rate study concerning prescription drug reimbursement costs. Soon thereafter, Medi-Cal retained the services of Myers & Stauffer LC to conduct such a study. (Robben Decl. Exs. 33-34, 35 at 93.) The Myers & Stauffer studies were completed in August of 2002. (*Id*.) It confirmed "the existence of 'mega-spreads' on generic drugs including many of the Subject Drugs." (Defs. Jt. Reply Br. at 8.)

- California thereafter "made only a modest reduction in ingredient cost reimbursement, while at the same time increasing its dispensing fee. Even though deeper discounts would have resulted in greater savings, DHS chose to endorse AWP minus 17 percent because it was, as one Medi-Cal official describes it, 'the most defensible position in the event of litigation.'" (*Id*.)

Based upon the foregoing, argue Defendants, "since January 1997, California has chosen to continue using compendia AWP to strike the appropriate balance between efficiency and economy and ensuring that Medi-Cal beneficiaries have adequate access to quality care, as required by *Orthopaedic Hospital*." (*Id*.) Consequently, "after the Ninth Circuit's decision in *Orthopaedic Hospital*, the causal link between Defendants' price reporting practices and California's alleged damages is broken." (*Id*. at 4.)

Even accepting, solely for the sake of argument, that all of Defendants' asserted facts are true, their conclusions are meritless as a matter of law.

A. Orthopaedic Hospital Does Not Apply to Drug Reimbursement Rates.

Orthopaedic Hospital addressed reimbursement rates for hospital outpatient services, *exclusively*. Nowhere in the 1997 opinion does the Ninth Circuit discuss, refer to, or otherwise consider reimbursement rates for prescription drugs; indeed, the court did not address the applicability of *Orthopaedic Hospital* to drug reimbursement until the issuance of *Indep. Living Ctr. of S. Cal., Inc. v. Maxwell-Jolly*, 572 F.3d 644, 651-52 (9th Cir. 2009). The instant case is, of course, limited to false claims arising from fraudulent AWPs from 1994 through 2004; hospital outpatient services reimbursement rates are thus irrelevant. Accordingly, while *Orthopaedic Hospital* may militate compliance with its interpretation of Section 30(A) of the Medicaid Act with respect to post-1997 reimbursement rates for hospital outpatient services, California was under no similar legal mandate with respect to prescription drug reimbursement rates until the 2009 issuance of *Maxwell-Jolly*. As such, it is difficult to see how *Orthopaedic Hospital*—again, a case that was issued in 1997 and had nothing to do with prescription drug reimbursement rates—stands for the type of "causation-negating" legal precedent that Defendants try to make it out to be.

In any event, while *Orthopaedic Hospital* may have interpreted Section 30(A) as imposing certain affirmative obligations on Medi-Cal with regard to hospital outpatient services reimbursement rate adjustments, in no way did the Ninth Circuit find that federal law denies California (or any other state Medicaid program within the Ninth Circuit's jurisdiction) the ability to enforce and recover on the statutes and regulations relevant to its reimbursement program. In sum, whether California has or has not complied with the Ninth Circuit's mandate in *Orthopaedic Hospital* is not only fundamentally irrelevant, but is also an open question, as this Court has never adjudicated this precise issue as it applies to drug reimbursement rates. In any

event, the holding in *Orthopaedic Hospital* provides Defendants with no justification or excuse for reporting grossly inflated AWPs as alleged by Plaintiffs.

B. California Need Not Demonstrate Any Damages to Prevail Against Defendants Under the CA FCA.

Through Dr. Leitzinger's[4] testimony and the other facts and arguments presented in Plaintiffs' Motion for Partial Summary Judgment and in their Opposition to Defendants' Joint Motion for Partial Summary Judgment, Plaintiffs have overwhelmingly demonstrated that Defendants directly and proximately caused California's alleged overpayments for the Subject Drugs. However, California need not show (or even allege) *any* damages whatsoever to prevail in this action. Like the Federal Act, the CA FCA proscribes the presentment of false claims, regardless of whether the State sustains any damages as a result. CAL. GOV'T CODE § 12651(a); *see United States ex rel. A+ Homecare, Inc. v. Medshares Mgmt. Group, Inc.*, 400 F.3d 428, 445-46 (6th Cir. 2009) (the FCA imposes liability "upon presentment of a false or fraudulent claim, rather than actual payment on that claim"). The CA FCA prescribes civil penalties of $5,000 to $10,000 for each false claim irrespective of whether California suffered any actual damages. *See State v. Altus Finance*, 36 Cal. 4th 1284, 1299 (2005) (CA FCA "authorizes civil penalties for attempts to misappropriate public funds that were not in fact completed by payment from the treasury"). As a matter of law, then, California need not demonstrate a causal link

[4] As an aside, in their joint reply brief, Defendants complain that California "fails to explain why Prof. Leitzinger includes a 25 percent markup over his calculated quarterly average of prices received by Defendants from wholesalers in his 'overpayment' calculations. The 25% markup … is at odds with California's argument that it only intended to reimburse providers at their actual cost of a drug. [Citation.]" (Def. Jt. Reply at 6, n.4.) This is frivolous and, for Defendants, self-defeating. As indicated in his deposition, Dr. Leitzinger testified that he included the 25 percent margin at the direction of Plaintiffs' counsel because "the State, in looking at some of the decisions that Judge Saris issued, came to believe it was appropriate to build in a 25 percent markup." (Declaration of Nicholas N. Paul in Support of Sur-Reply, Ex. 27 (9/24/09 Leitzinger Dep.), at 325:15-20.) This 25% markup above WAC (i.e., the "Hartman Speed Limit"), which in effect *reduces* Defendants' ultimate damages exposure to California, has been approvingly referred to by this Court and the First Circuit in a related matter. *See In re Pharm. Indus. Average Wholesale Price Litig*, 582 F.3d 156, 183-184 (1st Cir. 2009); *In re Pharm. Indus. Average Wholesale Price Litig*., 491 F. Supp. 2d 20, 92 (D. Mass. 2007).

between its alleged $277 million in overpayments and Defendants' false AWPs for the purpose of establishing Defendants' liability under the CA FCA; rather, Plaintiffs need only demonstrate that Defendants knowingly published false AWPs that they knew Medi-Cal would use for the purposes of prescription drug reimbursement.

Accordingly, even assuming Plaintiffs could not demonstrate a single dollar's worth of damages resulting from the 24.5 million actionable false claims at issue in this case (*see* Paul Decl. Exs. 24-26), Defendants still could not escape liability for their fraud. Plaintiffs have amply demonstrated, through their moving papers and subsequent opposition and reply briefs, that Defendants published grossly inflated AWPs that they knew California would use for reimbursement purposes. California relied upon and used those AWPs, thereby causing it to reimburse providers significantly more than their actual cost of acquiring the Subject Drugs. Defendants were charged with knowing that AWP in California was supposed to bear a reasonable relationship to the providers' actual cost of acquisition. *See, e.g., Heckler v. Community Health Services of Crawford Cty., Inc*., 467 U.S. 51, 64 (1984); *United States v. Mackby*, 261 F.3d 821, 828 (9th Cir. 2001). Thus, regardless of any issues raised in *Orthopaedic Hospital* concerning provider participation rates or beneficiary access, the fact that Defendants caused California to reimburse providers for the Subject Drugs at rates well beyond any reasonable estimation of the providers' actual cost of acquisition is all that California need show in order to demonstrate Defendants' liability under the CA FCA. The ultimate determination of damages and civil penalties is another matter entirely.

C. Defendants Interpretation of Orthopaedic Hospital *Would Create an Absurd Result.*

Defendants' arguments to the contrary notwithstanding, *Orthopaedic Hospital* stands for one premise: i.e., that pursuant to section 30(A) of the Medicaid Act, Medi-Cal must adjust its

hospital outpatient services reimbursement rates in a manner consistent with Medicaid's goals of efficiency, economy, quality service, and access, and must conduct a rate study before adjusting hospital reimbursement rates. *Orthopaedic Hospital*, 103 F.3d at 1500. Under no circumstances can it reasonably be said that the Ninth Circuit ever intended to relieve drug manufacturers—Defendants among them—of their obligation to report accurate AWPs to the compendia knowing such prices are used by California and other state Medicaid programs to reimburse providers. That, however, is precisely what Defendants are encouraging this Court to find—i.e., that *Orthopaedic Hospital*, coupled with California's attempts to administer its Medicaid program consistent with federal and state law, affirmatively released Defendants from their legal obligation to report accurate AWPs *for all time*. This would clearly be an absurd result.[5]

Regardless of how they attempt to dress it up, Defendants' long-rejected argument that AWP is whatever they assert it to be remains a dead letter. Contrary to their legal obligations under California law, Defendants reported false AWPs. To its detriment, California used those fraudulently inflated prices in connection with its reimbursement program for prescription drugs. Defendants are therefore liable for causing the submission of false claims.[6]

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[5] It is useful to consider what Medicaid reimbursement for prescription drugs would look like under a regime controlled by Defendants' "can't lose" theory of drug pricing predicated upon their curious interpretation of *Orthopaedic Hospital*. According to Defendants, regardless of what they reported for a drug's AWP, whether it be 100, 1000, or 10,000 times greater than the providers' actual cost of acquisition, *any* discount-adjustment to Medi-Cal's reimbursement rate that fell below the "mega-spread" would necessarily amount to a ratification of Defendants' otherwise fraudulent AWPs, thus vitiating causation.

[6] Several factors made it particularly difficult for California to abandon its reliance on reported AWPs during the case-relevant period (1994-2004), but the relevant period did include two consecutive reductions in the discount applied to AWP-based reimbursement (from minus 5% to minus 10% in 2002, then to minus 17% in 2004). *First*, Medi-Cal had used AWPs for many years, and there would have been significant costs and administrative burdens in switching to an alternative methodology. *Second*, the simple reality is that pharmaceutical pricing is oblique and there were no clearly preferable alternatives. As the California Assembly Committee on Health noted in its March 11, 2003 report: "[T]he 'true' cost of prescription drugs has grown increasingly elusive. … For any individual drug, only three of the ten prices are published, and only the Average Wholesale Price (AWP) is widely available and includes all drugs." (Plaintiffs' Statement of Additional Undisputed Facts In Opposition to Defendants' Motions for Partial Summary Judgment (docket no. 6790) (hereinafter "CA SAOF Defs.") at ¶ 22.) *Third*, reimbursements based on discounted AWPs worked reasonably well for the branded drugs that made up 80% of Medi-Cal's pharmacy costs. And Medi-Cal legitimately relied on CMS' FULS to correct problems with generic pricing. *Fourth*,

D. Defendants Misstate the Findings of the Court in **Fassberg.**

Defendants cite to the California appellate court case of *Fassberg Construction Co. v. Hous. Auth. of City of Los Angeles*, 152 Cal. App. 4th 720 (2007) for the proposition that California's claimed overpayments are uncollectable under California law. Defendants misread *Fassberg*, and apparently omit from their analysis critical facts that support Plaintiffs' theory of damages in this action.

In their joint reply brief, Defendants observe that the defendant in *Fassberg* falsely certified to the government that it had paid its workers the prevailing rate, pursuant to a construction contract it had entered into with the Housing Authority of the City of Los Angeles. *Id*. at 728, 748-49. (Defs. Jt. Reply Br. at 5-6.) Defendants continue:

> [T]he court rejected the Housing Authority's argument that the correct measure of damages was "the difference between the total amount paid … and the amount it would have paid if the [alleged false statements] had been truthful" and instead held the correct measure of was "the amount that will compensate for all of the loss or harm proximately caused by the [false claim or false statement]." *Id*. at 748-49. Accordingly, the court vacated the jury's damage award to Los Angeles, because, "[t]he Housing Authority received what it paid for and accepted under the terms of the contract: a completed work of construction. … The Housing Authority is not entitled to disgorgement of amounts paid under the contract as damages … because those amounts do not reflect an actual loss of harm to the Housing Authority. *Id*. at 749.

(Defs. Jt. Reply Br. at 6.) Based upon this, Defendants assert that California's measure of damages in the instant case—i.e., the difference between what California actually paid in reimbursement for the Subject Drugs and the amount it would have paid had Defendants reported

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it is noteworthy, that there is a history of pharmaceutical interests thwarting Government efforts fix the system. For example, in 2004, the Legislature revised section 14105.45 of the Welfare & Institutions Code to base generic reimbursement rates on "average sales prices." But Medi-Cal was unable to obtain accurate information from manufacturers and could not implement that change. (CA SAOF Def. ¶¶ 24, 25). Given all of these factors, it is eminently fair to hold Defendants liable for their fraudulent AWPs, at least through the 2004 cut-off of California's case.

the "real" AWPs calculated by Dr. Leitzinger—is "precisely the measure of damages the court in *Fassberg* held was improper, namely the difference between what California actually paid and what California contends it would have paid were it not for Defendants' allegedly 'false' statements." (Defs. Jt. Reply Br. at 6-7.) This is demonstrably inaccurate and misleading.

What Defendants fail to reveal about *Fassberg* is the crucial and obvious fact that defendant Fassberg *underpaid* its workers, which in turn resulted in no actual monetary loss to the Housing Authority. Noted the court, "[w]e conclude that the award of $455,000 in damages for false claims was based on the *underpayment* of prevailing wages for which the Housing Authority was not entitled to recover damages." *Id*. at 748 (emphasis added). Indeed, the omitted portion of *Fassberg* from Defendants' quote (as represented by Defendants' insertion of an ellipsis) is particularly telling. Properly quoted, the case in its entirety provides as follows:

> The ordinary measure of damages under California law for breach of an obligation not arising from a contract is the amount that will compensate for all of the loss or harm proximately caused by the breach. [Citation.] The Housing Authority received what it paid for and accepted under the terms of the contract: a completed work of construction. *The Housing Authority has not shown that it paid the workers any part of the wages shortfall or has been sued for such a recovery. It has not shown that the failure to pay prevailing wages to some of the workers on the project increased the cost of construction paid by the Housing Authority, impaired the value of the completed project, or caused any cognizable loss or harm to the Housing Authority.* The Housing Authority is not entitled to disgorgement of amounts paid under the contract as damages (trebled under [the CA FCA]) because those amounts do not reflect an actual loss or harm to the Housing Authority. [Citations.]

Fassberg, 152 Cal. App. 4th at 749 (emphasis added). In other words, though one might never know it from reading Defendants' recitation of the case, the court in *Fassberg* found that because the Housing Authority neither paid the shortfall in wages to the workers nor was otherwise

obligated to indemnify Fassberg for its underpayment, the Housing Authority suffered no monetary damages that could be trebled under the CA FCA.

Unlike *Fassberg*, Plaintiffs' action against Defendants is an *overpayment* case, in that but for Defendants' fraudulent AWPs, California would not have made at least $277 million in overpayments for the Subject Drugs. Thus, unlike the Housing Authority in *Fassberg*, which "received what it paid for and accepted under the terms of the contract," *id*. at 749, California, under the terms of its prescription drug reimbursement statute, paid substantially *more* than was necessary for what it actually received.[7] As demonstrated here, as well as in Plaintiffs' Motion for Partial Summary Judgment and in Plaintiffs' Opposition to Defendants' Motion for Partial Summary Judgment, Defendants are the causal factor behind each of those overpayments. Accordingly, it is without question that Defendants are, as a matter of law, liable for California's loss, plus penalties and multipliers under the CA FCA.

II. DEFENDANTS' STATEMENTS OF LAW REGARDING GOVERNMENT KNOWLEDGE AND SCIENTER, AND THEIR ASSERTION THAT CALIFORNIA'S CLAIMS AFTER AUGUST 2002 ARE BARRED BY THE STATUTE OF LIMITATIONS, ARE INACCURATE.

This Court recently underscored the rigorous disclosure and approval standards Defendants must meet to escape liability under a government knowledge defense: "To prevail on a government knowledge defense, Defendants must produce admissible evidence that [California] or its agencies *knew the actual true facts*, and that they ordered, asked for, approved,

[7] Notably, while the court in *Fassberg* reversed the Housing Authority's award of trebled damages for the alleged $455,000 in underpaid wages, it noted that Fassberg might nevertheless be subject to paying damages with respect to its false claims liability. "We conclude further, however, that Fassberg has not shown that the evidence compels the conclusion that the Housing Authority suffered no damages as a result of false claims or false records or statements…. Fassberg alludes to the denial of its motion and argues that the damages award cannot be affirmed based on the underpayment of wages, but offers no meaningful argument why the evidence compels the conclusion that the Housing Authority suffered no damages at all resulting from false claims or false records or statements. The question of such damages, if any, can be decided in a new trial in connection with the question whether Fassberg made false claims and, if so, how many." *Fassberg*, 152 Cal. App. 4th at 750.

or decided as a policy matter to acquiesce *in the Defendants' reporting of false prices*." *In Re Pharm. Indus. Average Wholesale Price Litig.(New York)*, No. 01-12257, at 25 (D. Mass. Jan. 27, 2010) (order granting and denying motions for summary judgment) (docket no. 6863) (citation omitted) (emphasis added).

Consequently, the core inquiry guiding this Court's resolution of Defendants' government knowledge argument is whether there is *any* evidence that any of the Defendants were instructed by California to believe that the falsely inflated AWPs they reported were exonerated, which in turn requires admissible evidence showing that Defendants were open and cooperative with the *relevant*[8] California officials in fully informing such officials of the nature and full extent of their fraudulently inflated AWPs. There is no such evidence.

While Defendants have claimed that California officials either learned or could have learned some of the facts about their reported prices, no Defendant has submitted any evidence showing: (a) that California was fully informed of all material facts concerning its reported prices (i.e., that the Defendant's reported AWPs not only were falsely inflated, but had no relationship to actual market prices); (b) that the Defendant fully cooperated with California to inform it about the nature of its false AWPs; or (c) that the Defendant was somehow invited by California to report *false* (not just 'inflated") AWPs. On these undisputed facts, no Defendant can show that it did not knowingly cause false claims to be submitted to California.

[8] Under *United States v. Lachman*, 387 F.3d 42 (1st Cir. 2004), Defendants cannot rely on non-public or informal understandings or statements of Medi-Cal officials regarding California's reimbursement policies. The court noted that it would "look to agency interpretations only when the statute or regulation remains ambiguous after we have employed the traditional tools of construction." *Id.* at 54. Second, the court held that even under those circumstances, "agency interpretations are only relevant if they are reflected in public documents. . . . the same requirements [as for interpreting statutes] of public accessibility and formality are applicable in the context of agency interpretations of regulations." *Id.* When confronted with evidence almost identical in type to what defendants present here, the First Circuit held, "The non-public or informal understandings of agency officials concerning the meaning of a regulation are thus not relevant. The affidavits here of former and present agency officials as to the agency's non-public understanding of the regulation do not remotely satisfy the requirements of formal and public accessibility." *Id.*

Defendants claim the actions taken in California during the relevant period constitute a record which gives them a free pass on their deliberately fraudulent AWPs. In advancing such claim, Defendants rely on a single federal False Claims Act case which involved a dispute over statutory interpretation, *United States ex rel. Englund v. Los Angeles County*, No. CIV S-04-282 LKK/JFM, 2006 WL 3097941 (E.D. Cal. Oct 31, 2006) (Defs. Jt. Reply Br. at 10-11). Defendants also insist that California's claims after August 2002 are barred because of the Myers & Stauffer report, citing *Englund* and *United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931 (10th Cir. 2008). (Defs. Jt. Reply Br. at 12-16.) As explained below, Defendants misconstrue both the record in the instant case and the holdings in the caselaw upon which they rely.

A. California Had An Affirmative Policy Of Paying At Estimated Acquisition Cost At All Times During The Relevant Period, As To Which AWP Was An Explicitly Stated Benchmark.

As a threshold matter, Defendants substantially distort the record in claiming that, notwithstanding the Myers & Stauffer report, the California Legislature knowingly set drug reimbursement at a rate that would continue to result in payments which significantly exceeded providers' actual costs. (Defs. Jt. Reply Br. at 11.) To the contrary, the record is clear that California's stated policy was not to overpay for drugs for any reason, but rather to reimburse for drugs based on an estimate of providers' acquisition costs and to do so as accurately as possible. (CA SOAF Defs. ¶¶ 18, 19.) Defendants ignore the fundamental reality that the Medi-Cal reimbursement methodology and governing rates during the relevant time period were established pursuant to a formal rulemaking proceeding in 1989, and were then subsequently modified by statute. Indeed, when, in 1989, California moved from AWP to AWP-5% drug reimbursement, DHCS expressly concluded that such reimbursement rate was set because "the State must come as close as possible to the actual acquisition cost. The AWP-5% program is the State's best estimate of this cost." (CA SOAF Defs. ¶ 19.)

In 2002 the California Legislature did not yet have, and therefore could not rely upon, the Myers & Stauffer report when changing the Medi-Cal prescription drug reimbursement rate from AWP-5% to AWP-10%. (CA SOAF Defs. ¶¶ 5, 8, 10, 11, citing California's Budget Trailer Bill AB 442.) Although the 2004 rate change from AWP-10% to AWP-17% *was* based on the August 2002 Myers and Stauffer report, the AWP change necessarily applied to the entire range of drugs in the Medi-Cal formulary, as to which 80% of expenditures were for branded drugs that, generally, did not exhibit the type of fraudulently inflated AWPs at issue in this case. In other words, the Legislature was attempting to set the correct balance of reimbursement across a massive range of drugs (consisting of approximately 26,000 NDCs), not the 394 NDCs at issue in this case. (CA Dey SOF ¶ 11, 23, CA Mylan SOF ¶ 22, CA Sandoz SOF ¶ 22.) In short, *no California legislator or staffer ever expressly or implicitly indicated any acceptance of inflated or untruthful AWPs*. (CA SOAF Defs. ¶ 16.)

Nor would it have been reasonable for the Legislature to have had knowledge of Defendants' fraudulent prices. In generally complaining about the costs of prescription drugs in March 2003, the Legislature noted that each "drug sold by a manufacturer is subject to multiple prices, *and little is known publicly about this pricing information*." (CA SOAF Defs. ¶ 22, emphasis added.) Indeed, as Defendants' own expert admits, understanding the measure of an appropriate discount off Defendants' AWPs—which was necessary to accurately estimate the prices generally and currently paid by providers—required an understanding of the prices *actually paid by those providers*. (CA SOAF Defs. ¶ 17.) As this Court has previously underscored, "finding out the true price of a drug is no easy matter because drug pricing terms are protean." *Massachusetts v. Mylan Labs*., 357 F. Supp. 2d 314, 323 (D. Mass. 2005).

Defendants, of course, knew what those actual prices were, as their own business records reflected the actual prices at which Defendants' drug products were being acquired by providers. (CA Dey SOF ¶ 23, CA Mylan SOF ¶ 22, CA Sandoz SOF ¶ 22.) Indeed, at all relevant times Defendants closely monitored the prices at which they sold their products to wholesalers, as well as to large chains and group purchasing organizations with whom Defendants contracted. *Id.* Notwithstanding their knowledge of the real prices that providers were paying, however, each Defendant virtually always reported AWPs creating spreads in excess of 100%, most often in excess of 300%. (CA Dey SOF ¶ 25, CA Mylan SOF ¶ 24, CA Sandoz SOF ¶ 24.)

The systematic and deliberate failure of Defendants to report accurate and honest AWPs was not only manifestly injurious to California, but also served to aggravate the problem of Medi-Cal's reimbursement overpayments, in that it required the expenditure of time and resources to implement the legislative fixes Defendants now characterize as evidence of "knowing" acceptance of their fraud. (CA SOAF Defs. ¶¶ 1, 13, 14.) Defendants' assertion in this regard is wholly specious. The record fails to support Defendants' claims that California had "an affirmative policy of using payments based on AWP to compensate providers for inadequate dispensing fees" (Defs. Jt. Reply Br. at 10); that California abjectly accepted Defendants' fraudulently inflated AWPs because it was incapable of effectuating policy changes to reduce its reimbursement, (*id.*); and that California was somehow forced to pay high reimbursement based upon the holding in *Orthopaedic Hospital* (Defs. Jt. Reply Br. at 11).

Defendants' Reply Brief manifests a dispositive fact: they are concededly unable to identify a single instance in which California expressly stated its understanding of the extent to which Defendants fraudulently inflated their AWPs on the drugs at issue, or a single instance in which California expressly stated its approval of those fraudulently inflated AWPs. Defendants

are consequently reduced to the flaccid assertion that "no false claims act liability will lie, even if government officials do not approve of the defendant's conduct" (Defs. Jt. Reply Br. at 10) merely because California did not reduce its reimbursement in the manner which Defendants insist was dictated by the Myers and Stauffer report (Defs. Jt. Reply Br. at 11-13). Other than *Englund* and *Orenduff*, Defendants cite to no authority for this proposition, and neither case withstands the weight of reliance placed upon it.

B. Defendants Misread Englund *And* Orenduff*, Two Cases Which Accentuate The Import Of Open And Complete Disclosure By A FCA Defendant As A Prerequisite To Any Invocation Of The Government Knowledge Defense.*

1. *Englund*

Englund arose when a qui tam plaintiff brought suit against Los Angeles County under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729, *et seq.*, alleging that the County made false claims and/or conspired with the State of California in order to receive unwarranted Medicaid funds. The United States declined to intervene. *Englund*, 2006 WL 3097941 at *1. As the court explained, the conduct at issue involved administrative policies undertaken by Los Angeles County under its Medicaid managed care program's use of the Selective Provider Contracting Program ("SPCP"). *Id.*[9] The relator alleged the county had saved money under the SPCP and had used the savings unlawfully by failing to demonstrate a "purpose," as required under the SPCP, when seeking matching "intra-governmental transfer" ("IGT") funds from the state and (ultimately) federal governments. In effect, the relator alleged that Los Angeles County failed to adequately account for its SPCP savings when seeking IGT transfers. *Id*. at *3-*4.

[9] Under the SPCP, *see* CAL. WELF. & INST. CODE §§ 14081 and 14087, savings were supposed to be achieved by replacing the regulatory model with a competitive model. California contracts with hospitals that provide services to Medicaid beneficiaries at competitively negotiated rates in lieu of Medicaid's traditional fee-for-service reimbursement. *Id.* The California Medical Assistance Commission ("CMAC") negotiated the rates with the providers, including the County. *Englund*, 2006 WL 3097941 at *1.

Unlike the instant case, in which the measure of fraud implicit in Defendants' deliberately inflated AWPs was never disclosed to the government, the *Englund* court found that Los Angeles' practices regarding its use of monies saved under the SPCP were explicitly known at all times to all parties to the litigation, including CMS, the State, and the county. The dispute in *Englund* involved the relator's *interpretation of the law* regarding the use of SPCP savings (an interpretation shared by neither California, the United States nor Los Angeles County), and not—as is the case here—the impact of deceptively and fraudulently inflated drug manufacturer AWPs. As the *Englund* court explained:

> The County presents evidence that CMS was fully aware that the County was using a legal loophole to maximize the amount of federal funding the State could receive for Medicaid services. As the County explained in its brief, "CMS did not like the IGT programs, to be sure, *but they were legal, enjoyed statuary protection, and helps* [sic] *to preserve the viability of public safety-net hospitals in the absence of national health insurance.*"

Englund, 2006 WL 3097941 at *13 (emphasis added). The court found that relator's claims necessarily failed on summary judgment because CMS and the federal government knew, at all times, exactly what the county was doing. *Id.* at *13-*16. Using IGTs to maximize the federal contribution was not unique to either the county or to California, and was legal. *Id*. at *13. As the *Englund* court concluded, the relator simply could not demonstrate that the county had ever concealed anything from the State or the federal government:

> In the case at bar, the County submits extensive evidence that officials on both the State and Federal levels *were well aware of the County's actions and understood the alleged "scheme" to be legal*. Thus, even if the County caused the State to submit a "false" claim, the government's knowledge negates the County's intent.

Englund, 2006 WL 3097941 at * 13 (emphasis added).

Englund is therefore of no value to Defendants, based upon two critical distinctions: 1) unlike the county's administrative actions at issue in *Englund*, which were indisputably understood and approved by the federal government as lawful at all times, the conduct at issue in the instant case involves the inflation of prices relied upon by California to reimburse Medi-Cal providers for the drugs dispensed to needy beneficiaries, and 2) unlike the facts in *Englund*, where the county's open and transparent procedures regarding SPCP savings and IGT transfers were never concealed and were understood at all times by CMS and the State, the drug manufacturer Defendants in this case at all times concealed their conduct from California, and have never made any disclosure of the extent to which they inflated their AWPs.

Englund thus offers no support for the suggestion that Defendants should enjoy any measure of protection for their fraudulent conduct simply because California generally had become aware (through means wholly unrelated to any disclosure from Defendants) that there were problems with the accuracies of AWPs for some generic drugs. As the Seventh Circuit explained in *United States ex rel. Durcholz v. FKW, Inc.*, 189 F.3d 542 (7th Cir. 1999), "[i]f the government knows *and approves of* the particulars of a claim for payment before that claim is presented, the presenter cannot be said to have knowingly presented a fraudulent or false claim." *Id.* at 545 (emphasis added). An Illinois district court, focusing on the conjunction in the preceding quotation, underscored its importance as follows:

> Judge Cudahy was the author of the opinion in *Durcholz.* On the panel were Judges Posner and Rovner. The Court of Appeals' conjunctive phrasing—"if the government knows *and* approves" would appear to have been purposeful and intended to signal that mere knowledge alone of illegality would not enable those who defraud the government from being able to draw a conjurer's circle around their illegality and insulate themselves from condign punishment. *Any other reading would make the conjunctive phrasing superfluous.*

United States ex rel. Tyson v. Amerigroup Ill., Inc., No. 02 C-6074, 2005 WL 3111972 at *6 (N.D. Ill. Oct 21, 2005) (first emphasis original, second added). In other words, *Tyson* specifically emphasizes that it is not enough that the government *knows* of illegal conduct; it must *also approve* of the conduct at issue in order for a defendant to avail itself of the insulation from liability vis-à-vis "government knowledge." *Id; see also, United States v. Southland Mgmt. Corp*., 326 F.3d 669, 682-83 n.9 (5th Cir. 2003) (en banc) (Jones, J., concurring) ("In principle, it would seem that the government's knowledge of a false claim would not be an effective defense if the person making the false statement did not know that the government knew it was false ...." (citing *Durcholz*, 189 F.3d at 544-45)).

Here, there are no facts in the record which demonstrate that California ever approved Defendants' practice of reporting fraudulently and grossly inflated AWPs; conversely, the record is rife with facts confirming that California *never* approved such fraudulent conduct. (CA SOAF Defs. ¶¶ 2, 12, 13, 15, 16 and 29.)

2. *Orenduff*

Equally unsuccessful is Defendants' attempt to seek support from *United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931 (10th Cir. 2008). In *Orenduff*, the defendants were New Mexico State University ("NMSU") administrators who had mistakenly relied on the federal government's misclassification of a university as a "minority institution" in response to solicitations from the government for grant proposals from minority institutions. *Id.* at 933-34. Relators alleged that defendants had falsely certified that NMSU was a Department of Education ["DoE")-designated "minority institution" eligible for Department of Defense ("DoD") set-aside contract grants. The court affirmed the district court's grant of summary judgment to defendants on relators' FCA claims, based in part on facts showing that at all times the United States had understood all the underlying facts regarding the contractual disconnect between NMSU and

DoD. The Tenth Circuit's explanation of the government's knowledge is significant, since it sets forth a factual situation markedly different that that present in the instant case:

> [T]he government knowledge inference is well-suited to the facts of this case, where both governmental knowledge *and* governmental cooperation are present. Here, the DoE had access to NMSU's enrollment data. Consistent with its statutory obligation, the DoE reviewed this data and repeatedly designated NMSU as a minority institution. Based upon these designations, the DoD invited NMSU to apply for set-aside contracts, confirming that NMSU satisfied the statutory criteria for its set-aside program so long as it appeared on DoE's minority institution lists. With no reason to distrust the very agency responsible for administering the set-aside program, defendants then relied upon the DoD's assurances and invitations in certifying NMSU as a minority institution.
>
> It is true, as relators point out, that defendants never expressly informed the DoD that NMSU did not meet, or did not have the data to determine whether it met, the criteria referenced in 10 U.S.C. § 2323(a)(1)(C). *However, the undisputed evidence in the record indicates that NMSU was completely forthcoming with the DoE-the very agency on whose analysis the DoD uncritically relied.* For instance, NMSU submitted data to the DoE on an annual basis. This data contained information about NMSU's student enrollment, including information concerning total institutional enrollment, total minority enrollment, and need-based financial assistance. *Tellingly, there isnothing in the record to suggest that this data, or any other data submitted on behalf of NMSU, was materially inaccurate.*

Orenduff, 548 F.3d at 953 (emphasis added). The data that DoD reviewed, as submitted by NMSU, was in all respects factually accurate. *Id*. at 949-951. This is in stark contrast to the case at bar, in which Defendants never submitted accurate AWPs to California and were hardly "completely forthcoming" about the fraudulently inflated AWPs they reported throughout the relevant time period. As the court in *Orenduff* explained, even an "inferential" government knowledge defense rests on the quality and extent of the disclosure made to the government, and in any event is not dispositive as to the elements of falsity and scienter:

> It is only an inference. It does not *automatically* preclude a finding of scienter. *United States ex rel. Kreindler & Kreindler v. United Tech.*

> *Corp.*, 985 F.2d 1148, 1156 (2d Cir.1993) ("[T]he defendant's knowledge of the falsity of its claim ... is not automatically exonerated by any overlapping knowledge by government officials."); *see Southland Mgmt. Corp.*, 326 F.3d at 682 n. 9 (Jones, J., concurring) ("Courts have qualified the importance of government knowledge by stating that it may not always provide a conclusive defense to the claimant"); *United States v. Newport News Shipbuilding, Inc.*, 276 F.Supp.2d 539, 564 (E.D.Va.2003) ("A contractor's disclosure ... to the government is relevant, not because government knowledge of a misrepresentation shields a contractor from liability, but because evidence of disclosure may 'point[ ] persuasively away from any conclusion that [the contractor] made a knowing misrepresentation.' ") (quoting *X Corp. v. Doe*, 816 F.Supp.1086, 1094 (E.D. Va. 1993)). *The proper focus of the scienter inquiry under § 3729(a) must always rest on the defendant's "knowledge" of whether the claim is false, a knowledge which may certainly exist even when a government agency misinterprets its own regulations and chooses-with full comprehension of the facts-to pay a false claim.*

Id. at 952-53 (first emphasis original, second added). Here, Defendants knew at all times that their fraudulently inflated AWPs bore no resemblance to prices generally and currently paid by providers for their drugs (*see* CA Dey SOF ¶ 23; CA Mylan SOF ¶ 22; CA Sandoz SOF ¶ 22), and no Defendant ever made any disclosure to California about the fact or extent of its inflated AWPs (CA SOAF Defs. ¶ 29). More specifically, Defendants have failed to show a genuine dispute of fact as to the question of whether there was ever any disclosure of information by Defendants sufficient to show that they did not knowingly cause Medi-Cal to use fraudulently inflated AWPs to pay the millions of drug reimbursement claims at issue in this case. As discussed below, Plaintiffs' evidence establishes there was no such disclosure by Defendants during the relevant period. As the *Orenduff* court explained, "[t]he proper focus of the scienter inquiry under [the False Claims Act] must always rest on the defendant's "knowledge" of whether the claim is false, *a knowledge which may certainly exist even when a government agency misinterprets its own regulations and chooses-with full comprehension of the facts-to pay a false claim.*" 548 F.3d at 953 (emphasis added).

C. California's Claims Are As Viable After 2002 As Before 2002.

Apparently conceding that the 2002 Myers & Stauffer report and relator's amended complaint jointly established the fact that the AWPs for "many of the Subject Drugs at issue in this action" had "documented so-called mega-spreads," "some of which exceeded 1000 percent," (Defs. Jt. Reply Br. at 12), Defendants allege that California's claims fail after 2002 because "California's arguments about the absence of some express approval misstate the applicable law, and are not sufficient to create a triable issue of fact." *Id*. Defendants again rely exclusively on *Englund* and *Orenduff* to suggest that they should somehow be "able to draw a conjurer's circle around their illegality and insulate themselves from condign punishment," *Tyson*, 2005 WL 3111972 at *6, on grounds that the burden was on California to detect Defendants' fraud by spending considerable sums of money to conduct pricing surveys such as those undertaken by Myers & Stauffer (*see* CA SOAF Defs. ¶ 32). Defendants continue to misconstrue the law. As previously explained, the dispute in *Englund* involved the relator's interpretation of the law regarding what was actually the completely lawful use of SPCP savings by the county. *Englund*, 2006 WL 3097941 at * 13. *Englund* is thus wholly inapposite to the instant matter, unless Defendants can point to an interpretation of published law which would suggest that it is lawful for drug manufacturers to deliberately and fraudulently inflate the Average Wholesale Prices of their drugs notwithstanding the fact that both the state and federal governments depend on such AWPs to operate their reimbursement systems. *See id.* ("In the case at bar, the County submits extensive evidence that officials on both the State and Federal levels were well aware of the County's actions *and understood the alleged 'scheme' to be legal*. Thus, even if the County caused the State to submit a 'false' claim, the government's knowledge negates the County's intent" (emphasis added).) Moreover, as explained in *Tyson*, it is not enough that the government *knows* of illegal conduct. "The government must also *approve* of the defendant's

conduct at issue in order for a defendant to avail itself of the insulation from liability represented by 'government knowledge.'" *Tyson*, 2005 WL 3111972 at *6; *In Re Pharm. Indus. Average Wholesale Price Litig.(New York)*, No. 01-12257, at 25 (D. Mass. Jan. 27, 2010) (order granting and denying motions for summary judgment) (docket no. 6863)(same); s*ee also Southland Mgmt. Corp.*, 326 F.3d at 682-83 n.9 (Jones, J., concurring) ("[I]it would seem that the government's knowledge of a false claim would not be an effective defense if the person making the false statement did not know that the government knew it was false . . . .") (citation omitted).

Defendants' argument is further undercut by their insistent attempt to transform the Myers & Stauffer reports into documents of purportedly dispositive significance. (Defs. Jt. Reply Br. at 12.) The Myers & Stauffer reports were the result of California Senate Bill 393 (CA SOAF Defs. ¶ 5; Robben Decl. Ex. 33 at 3), which "require[d] the State Department of Health Services to conduct a study of the adequacy of Medi-Cal pharmacy reimbursement rates, including the cost of providing prescription drugs and services."[10] (*Id.*) While the Myers & Stauffer reports may have been relied upon to some extent by the California Legislature to justify a rate change in *2004*, at the end of the relevant period, the plain language of SB 393 makes clear that the reports were never intended to identify the specific rate at which Medi-Cal should reimburse providers.

D. AWP Was Both Defined And An Explicitly Stated Benchmark For EAC.

Consistent with the industry stance adopted early in this litigation, Defendants continue to obdurately insist that California never "defined AWP as anything other than a price listed in compendia." Defendants thus complain, in essence, that AWP is really whatever they report it to

be, in other words, that Defendants needed no statutory approval to report their AWPs as "something other than the final net cost to a provider." (Defs. Jt. Reply Br. at 14-15.)

To embrace this rhetorical flourish, an otherwise careful reader must irrationally excise whole sentences out of the pertinent regulation and statute. In a formal rulemaking proceeding held 21 years ago (i.e., in September 1989), DHCS revised its reimbursement rate to AWP-5%. In making that change, DHCS expressly concluded that "the State must come as close as possible to the actual acquisition cost. *The AWP-5% program is the State's best estimate of this cost*." (CA SOAF Defs. ¶ 19.)

Since then, pursuant to the applicable statute and regulation, Medi-Cal has been required to reimburse pharmacy providers for the cost of a dispensed drug product at the lesser of several amounts, one of which is the product's Estimated Acquisition Cost ("EAC"). CAL. WELF. & INST. CODE §§ 14105.46 (eff. Sept. 30, 2002 – August 15, 2004); 14105.45 (eff. Aug. 16, 2004); CAL. CODE REGS. tit. 22, § 51513. EAC, in turn, has at all relevant times been specifically set at the products' AWP, as published by the Department's primary reference source, First DataBank ("FDB"). *Id*. The California regulation and statute therefore expressly used reported AWPs as a means to determine providers' estimated acquisition costs for Defendants' drug products. Any possible doubt Defendants may have had about the meaning of the term AWP would have been eliminated by simply reading the regulation;[11] indeed, by electing to participate in Medi-Cal,

[11] Defendants are of course on record as having read the regulations closely enough to understand that California reimbursed based on AWPs, because, for instance, Sandoz knew it was necessary to report AWPs to FDB in order for its products to be reimbursed by third party payers, such as Medi-Cal, and FDB published the suggested AWPs reported by Sandoz as the AWPs for Sandoz's products. Sandoz was aware of Medicaid and Medi-Cal reimbursement policies in general, and Sandoz was aware that Medi-Cal reimbursed providers for pharmaceutical products based on the reported AWPs of the products. (CA Sandoz SOF ¶¶ 13-14, 20-21.) Mylan knew it had to report AWPs to FDB in order for Medi-Cal to reimburse providers dispensing Mylan products, and Mylan knew that FDB published the AWPs reported to it by Mylan as the AWPs for Mylan's drugs. (CA Mylan SOF ¶¶ 13-14.) Mylan was aware of Medi-Cal reimbursement policies, and Mylan was aware that Medi-Cal reimbursed providers for pharmaceutical products based, in part, on the reported AWPs of the products. (CA Mylan SOF ¶¶ 20-21.) Finally, Dey was not only specifically aware of Medi-Cal's reimbursement policies, but was particularly aware of

Defendants were required to familiarize themselves with the legal requirements, standards, and procedures of the program. *See, e.g.*, *Heckler*, 467 U.S. at 64 (1984), *North Mem'l Med. Ctr.*, 59 F.3d at 739 (8th Cir. 1995). Hence, as a matter of law, Defendants are charged with the knowledge that California used their reported AWPs to determine EAC—which was "the department's best estimate of the price generally and currently paid by providers for a drug product sold by a particular manufacturer or principal labeler in a standard package." CAL. WELF. & INST. CODE § 14105.45(a)(4) (West 2009). And, as this Court has previously found:

> The drug prices alleged by. . . [California] cross any reasonably drawn line between estimates which reasonably reflect prices paid by providers and estimates which are so grossly inflated when compared to actual acquisition costs that they are by their very nature fraudulent.

In re Pharm. Indus. Average Wholesale Price Litig., 478 F. Supp. 2d 164, 174 (D. Mass. 2007).

E. Defendants' Claim That They "Came Clean" to California With Pricing Disclosures Is Manifestly Devoid Of Substance.

Resigned to the fact that they are unable to demonstrate that California expressly and knowledgeably approved their practice of reporting fraudulently inflated AWPs so as to successfully assert a government knowledge defense, *see Tyson*, 2005 WL 3111972 at *6, Defendants' Joint Reply focuses on descriptions of purportedly "direct evidence of direct communications between the Medi-Cal program and each of the Defendants from which Defendants could readily conclude that California did not expect compendia AWP to approximate actual acquisition costs." (Defs. Jt. Reply Br. at 15.) This argument is vacuous:

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the reimbursement rates for Dey's products provided under Medi-Cal's AWP-based reimbursement system. (CA Dey SOF ¶¶ 20, 22.) Yet no Defendant has to date successfully explained how it was able to acquire such detailed knowledge of California's reimbursement system, without having also becoming aware that AWP was intended by California (as set forth in the exact same regulation and statute explaining that AWP was a reimbursement price) to be representative of estimated acquisition cost. This mystery is of no import, however, as Defendants were charged with understanding the rules and regulations governing Medi-Cal's drug reimbursement system. *Heckler v. Community Health Services of Crawford Cty., Inc.*, 467 U.S. at 64; *North Mem'l Med. Ctr. v. Gomez*, 59 F.3d 735, 739 (8th Cir. 1995).

none of the alleged "communications" constitute the type of full and candid disclosure required by caselaw, and Defendants' Reply exaggerates the content and substance of the information in these "communications."

Sandoz refers to quarterly letters reporting its AMPs to Medi-Cal (Defs. Jt. Reply Br. at 15), but at no time did California use AMPs to determine the actual acquisition cost paid by providers for Sandoz' drugs. Rather, as testified to by various employees of California's Department of Health Care Services, the AMPs received by California from Sandoz pursuant to Supplemental Rebate Agreements were used *only* for the calculation of such rebates. (*See*, Sandoz SOF ¶ 8.[12]) California did not use AMPs for any other purpose and, as stated in Plaintiffs' Opposition, California believed it could not do so pursuant to the confidentiality afforded to AMPs under federal law.[13] Moreover, this Court recently ruled that, as a matter of law, the fact that CMS had access to AMPs does not mean that CMS should have known that Defendants' published prices were false, because AMPs are statutorily prohibited from being used for reimbursement and must be held confidentially. The Court thus concluded that: "…CMS could not have used AMP data this in this way, and there is no evidence that it did. Moreover, the Medicaid statute required CMS to set its prices on the basis of Defendants' published prices, not the Defendants' AMPs, and thus there is no reason to believe that CMS looked to Defendants' AMP data in analyzing its reimbursements." *In Re Pharm. Indus. Average Wholesale Price Litig. (New York)*, No. 01-12257, at 28 (D. Mass. Jan. 27, 2010) (order

[12] Local Rule 56.1 Statement of Undisputed Facts in Support of Sandoz Inc.'s Motion for Summary Judgment (docket no. 6698).

[13] Moreover, in their Opposition to Sandoz's motion for summary judgment, Plaintiffs established that the Generic Pharmaceutical Association ("GPhA"), the generic manufacturers' trade association whose members include Sandoz, took the explicit position in correspondence sent to the United States Senate Committee on Finance, and to CMS, that AMPs *actually bore little relevance to market prices*, and were easily misinterpreted when payers, state agencies and consumers relied on them to indicate actual prices available in the marketplace. (Pls. Opp. at 8.)

granting and denying motions for summary judgment) (docket no. 6863) (citation omitted). The same reasoning applies here with equally dispositive force.

Mylan relies on a 2002 email from Medi-Cal official Mike Namba to Mylan employee Eric Belldina, in which Namba provides hypothetical examples of supplemental rebate calculations.[14] In this email Mr. Namba writes, "[s]ince the AWP is inflated, the manufacturer must rebate a very large amount to reach the net price." (Defs. Opp. at 29; Palermo Decl. Ex. S and T.[15]) The email and its attachments could hardly be interpreted by a reasonable jury as constituting *approval* of falsely inflated AWPs; at most, the materials amount to a generalized recognition of a pernicious problem with drug industry price reporting practices and an explanation of Medi-Cal's calculation of supplemental rebates on Estradiol Transderm, which is manufactured by *non*-Defendant Mylan Technologies and is not a Subject Drug. Since 1996, *none* of Defendant Mylan Pharmaceutical's drug products were subject to supplemental rebates. Moreover, Mylan presents no evidence that it ever relied on the 2002 email when inflating its AWPs, and nothing in the record suggests that California's collection of supplemental rebates in any way constituted acquiescence or ratification of Defendants' submission of false and inflated AWPs.

Similarly, Dey's claims that in 1999 it began sending to Medi-Cal letters indicating that its AWPs did not represent *actual* wholesale prices (Defs. Jt. Reply Br. at 16) hardly shield Dey from liability. These self-serving letters never disclosed to California that Dey was unlawfully reporting grossly inflated AWPs to FDB and California; indeed, submission of such letters is

[14] Defendants' Joint Reply refers to a Mylan employee's receipt of a supplemental rebate worksheet from Medi-Cal in 2003 (Defs. Jt. Reply Br. at 16), referring the reader to Defendants' Joint Opposition at pages 28-29. However, the latter brief places this event in 2002.

[15] Defendants' Joint Brief in Opposition to Plaintiffs' Motion for Partial Summary Judgment (docket no. 6801); Declaration of Christopher C. Palermo in Support of Defendants Mylan Inc. and Mylan Pharmaceutical Inc.'s Opposition to Plaintiffs' Motion for Partial Summary Judgment (docket no. 6798).

more akin to a burglar posting a Neighborhood Watch warning that "break-ins are on the rise." Moreover, California never informed Dey that its fraudulent AWPs were in any way acceptable. Rather, as discussed by Plaintiffs in their moving papers, applicable statutory and regulatory history make clear that California officials consistently used the term AWP in an effort to estimate the prices generally and currently paid by providers for pharmaceutical products. (*See* Plaintiffs' Memorandum in Support of Motion for Partial Summary Judgment (docket no. 6686) at 7-9.) As the First Circuit observed in *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156 (1st Cir. 2009), courts "[which] have found that government knowledge can prevent the defendant from forming the requisite state of mind (knowing that the claim is false or fraudulent) have done so only where the government's knowledge as to the true facts is extensive and in some cases where the government has actively approved of the underlying facts." *Id.* at 171 (emphasis added).

In sum, Defendants have provided no facts showing the degree of substantive, truthful and complete disclosure to California, or California's requisite and responsive approval of Defendants' conduct, so as to "insulate themselves from condign punishment." *Tyson*, 2005 WL 3111972 at *6.

III. DEFENDANTS HAVE NOT ESTABLISHED A DISPUTE OF FACT REGARDING THEIR LIABILITY FOR DAMAGES ON CLAIMS PAID AT THE FUL.

Defendants disclaim all liability for overpayments by Medi-Cal based on claims for Defendants' drugs when paid at the FUL[16] based on (1) assertions regarding the import of CMS's alleged "departure" from the formula for computing FULs, and (2) a factually barren

[16] *I.e.*, when California's "but-for" AWP as calculated by its expert, Dr. Leitzinger, demonstrated that California would have paid such claims at that lower AWP had Defendants reported it instead of their falsely inflated AWPs, under California's EAC-based "lesser of" reimbursement formula. The measure of damages for each such claim is the difference between the "but-for" AWP and the FUL at which the claim was actually paid.

hypothesis that California would never have reimbursed providers under the "but-for" AWPs computed by Dr. Leitzinger. (Defs. Jt. Reply Br. at 17-18.) Defendants fail to establish a material dispute of fact regarding their liability for damages for FUL-paid claims.

First, Plaintiffs do not dispute the fact that CMS set FULs, but have previously explained why the evidence before the Court hardly supports the conclusion that Defendants should be absolved from liability for their falsely inflated AWPs based on CMS's FUL-setting system. (*See* CA SOAF Defs. ¶¶ 27, 28, 33; Pls. Opp. at 27-29.) This Court recently terminated the viability of Defendants' arguments regarding alleged defects in CMS's FUL-setting system as a basis on which to disclaim such liability. *See In Re Pharm. Indus. Average Wholesale Price Litig. (New York)*, No. 01-12257, at 31-33 (D. Mass. Jan. 27, 2010) (order granting and denying motions for summary judgment) (docket no. 6863) (rejecting argument that because CMS exercised discretion in setting FULs, New York County plaintiffs were unable to show that defendants' falsely inflated prices caused CMS to set FULs at a level higher than would have been the case had defendants reported truthful WACs and AWPs). "Defendants not only caused FULs to be higher than necessary by inflating the array of prices that CMS relied upon in setting an appropriately priced FUL, but also by causing CMS to underestimate the quantity of drugs available at a given FUL, and thus to set higher FULs than necessary to achieve its goal of ensuring sufficient access to drugs." *Id*. at 33.

Defendants' second claim is speculative hyperbole forecasting the demise of Medi-Cal were it to pay claims at less than the FUL, i.e., at the expertly-calculated "honest" AWPs for Defendants' drugs, when those AWPs were lower than the FUL. Defendants have insisted in their motion, opposition, and reply that California would never have paid claims at less than the FUL because the program could not operate by reimbursing providers in such fashion. (Defs. Jt.

Reply Br. at 17.) But Plaintiffs, unlike Defendants, have provided irrefutable evidence that when Defendants' own AWPs were on rare occasions lower than the FULs in place for the same drugs, or when the provider's Usual and Customary Price was lower than the FUL, California in fact paid on those lower prices 100 percent of the time, i.e., at either the lower AWP (minus the statutorily prescribed discount of minus 5, 10 or 17%), or the provider's U&C. (Paul Decl. Ex. 11 (12/18/09 Leitzinger Declaration at 3.[17]) This fact demolishes Defendants' assertion that "there is no evidence in the record that California would ever have actually adopted these [lower AWPs as calculated by Dr. Leitzinger] to reimburse providers[.]" (Defs. Jt. Reply Br. at 17.)

If Defendants had reported truthful AWPs, and if those truthful AWPs would have required an additional "bump" to meet providers' operating costs, the California Legislature is obviously capable of adjusting reimbursement with an upward percentage addition if such was necessary to augment provider reimbursement for the Subject Drugs, just as it has with reimbursement for other drugs.[18] And the operational and policy decisions necessary to administer Medi-Cal's drug reimbursement benefit, of course, are the purview of California, not Defendants. Defendants have never provided one shred of evidence that Medi-Cal's drug reimbursement system would have been crippled had they not reported fraudulently inflated AWPs.

CONCLUSION

[17] Defendants complain that the approximately 374,000 instances in which California paid claims for the Subject Drugs at less than the FUL represent a mere 1.3% of the 28 million claims at issue. (Defs. Jt. Reply Br. at 18, fn. 8.) That percentage of claims in which the AWPs for the Subject Drugs was less than the FUL indeed looks tiny, but that is, of course, the inevitable and logical result of Defendants' systematic and fraudulent inflation of their Subject Drugs' AWPs throughout the relevant period of 1994-2004.

[18] *See, e.g.*, CAL. WELF. & INST. CODE § 14105.86 (West 2010) (applying a 120% markup to Average Sales Price, for blood factor drug reimbursement.

For the foregoing reasons, and the reasons set forth in Plaintiffs' Memorandum of Law in Support of their Motion for Partial Summary Judgment, Plaintiffs' Oppositions to Defendants' Joint and Individual Motions for Summary Judgment, and Plaintiffs' Reply brief, Plaintiffs respectfully request that the Court grant their motion for partial summary judgment.

Dated: January 29, 2010

Respectfully submitted,

EDMUND G. BROWN JR.
Attorney General for the State of California

By: */s/ Nicholas N. Paul*
NICHOLAS N. PAUL
Supervising Deputy Attorney General
RANDAL GLASER
Deputy Attorney General
Bureau of Medi-Cal Fraud and Elder Abuse
Office of the Attorney General
1455 Frazee Road, Suite 315
San Diego, CA 92108
Telephone: (619) 688-6026

Attorneys for Plaintiff,
STATE OF CALIFORNIA

THE BREEN LAW FIRM, P.A.

By: /s/ *James J. Breen*
JAMES J. BREEN
The Breen Law Firm, P.A.
5755 North Point Parkway, Suite 260
Alpharetta, GA 30022
Telephone: (770) 740-0008

BERGER & MONTAGUE, P.C.

By: /s/ *Susan S. Thomas*
SUSAN S. THOMAS
Berger & Montague, P.C.
1622 Locust Street
Philadelphia, PA 19103
Telephone: (212) 875-3000

KRAUSE KALFAYAN BENINK & SLAVENS LLP

By: /s/ *David Zlotnick*
DAVID ZLOTNICK
Krause Kalfayan Benink & Slavens, LLP
625 Broadway, Suite 635
San Diego, CA, 92101
Telephone: (619) 232-0331

Attorneys for Relator,
VEN-A-CARE OF THE FLORIDA KEYS, INC.

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on January 29, 2010, a copy to Lexis-Nexis for posting and notification to all parties.

/s/ Nicholas N. Paul
NICHOLAS N. PAUL